R.W. JOHNSON PHARM. RES. INST. USA

Individual Safety Report

3380751-0-00-01

For use by user facilities, distributors and manufacturers for MANDATORY reporting

Approved by FDA as MEDWATCH

MFR report # PRIUSA1999005930

FDA Use Only

A. Patient information

1. Patient identifier	2. Age at time of event: or Date of birth:	3. Sex	4. Weight
?-? (In confidence)	32 YR ??/???/??	☒ female ☐ male	UNK lbs or UNK kgs

B. Adverse event or product problem

1. ☒ Adverse event and/or ☐ Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)

☒ death ??/???/?? (mo/day/yr) ☐ life-threatening ☐ hospitalization - initial or prolonged ☐ disability ☐ congenital anomaly ☐ required intervention to prevent permanent impairment/damage ☐ other

3. Date of event (mo/day/yr): ??/???/??

4. Date of this report (mo/day/yr): 10/19/99

5. Describe event or problem

Report published in 1987 Annual Report of the American Association of Poison Control Centers National Data Collection System (case 338). A 32 year-old patient died while taking glutethimide and acetaminophen/codeine. Serum acetaminophen level was <5 ug/mL. Patient had prehospital (cardiac and/or respiratory) arrest. Intent of ingestion was unknown.

Additional information received 12-Oct-99: This 32 year old woman presented to the emergency department comatose, apneic, pulseless, and without a blood pressure after ingesting an unknown quantity of glutethimide and acetaminophen with codeine. The time of the ingestion was unknown. The patient was intubated and placed on a respirator. Her blood pressure was supported with intravenous fluids and dopamine. Naloxone was given without response. Gastric lavage was performed and activated charcoal and a cathartic were administered. A toxicology screen revealed a plasma acetaminophen level of less than 5 mcg/ml. Acetylcysteine therapy was initiated. Serum glutethimide level was reported as "high"

(Cont.)

6. Relevant tests/laboratory data, including dates

Serum acetaminophen level was <5 ug/mL, serum glutethimide level was reported as "high" and rising (laboratory value not reported)

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

unknown

1999

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)

#1 TYLENOL WITH CODEINE(tablet)(ACETAMINOPHEN/CODE-

#2 GLUTETHIMIDE(GLUTETHIMIDE)

(Cont.)

2. Dose, frequency & route used	3. Therapy dates (if unknown, give duration)
#1 unk, oral	#1 ??/???/??
#2 unk, oral	#2 ??/???/??

4. Diagnosis for use (indication)
#1 UNKNOWN
#2 UNKNOWN

5. Event abated after use stopped or dose reduced
#1 ☐ yes ☐ no ☒ doesn't apply
#2 ☐ yes ☐ no ☐ doesn't apply

6. Lot # (if known)
#1
#2

7. Exp. date (if known)
#1
#2

8. Event reappeared after reintroduction
#1 ☐ yes ☐ no ☒ doesn't apply
#2 ☐ yes ☐ no ☐ doesn't apply

9. NDC # - for product problems only (if known)

10. Concomitant medical products and therapy dates (exclude treatment of event)
No Concomitant Products Reported

D. All manufacturers

1. Contact office - name/address (& mfrng site for devices)

R.W. JOHNSON PHARM. RES. INST.
USA
DIV. OF ORTHO PHARMACEUTICAL CORP.
920 U.S. Route 202
P.O. Box 300
Raritan NJ 08869
USA
(Informing Unit)

2. Phone number: 908-704-4504

3. Report source (check all that apply)
☐ foreign ☐ study ☒ literature ☐ consumer ☒ health professional ☐ user facility ☐ company representative ☐ distributor ☐ other

4. Date received by manufacturer (mo/day/yr): 10/12/99

5. (A)NDA # 85-055
IND #
PLA #
pre-1938 ☐ yes
OTC product ☐ yes

6. If IND, protocol #

7. Type of report (check all that apply)
☐ 5-day ☒ 15-day ☐ 10-day ☐ periodic ☐ initial ☒ follow-up # 1

8. Adverse event term(s)
1) CARDIAC ARREST
2) APNOEA
3) COMA
4) RENAL FAILURE ACUTE
5) HEPATIC FAILURE
6) DISSEM. INTRAVASC.

(Cont.)

9. Mfr. report number
PRIUSA1999005930

E. Initial reporter

1. Name, address & phone #

Dr. Toby L. Litovitz
National Capital Poison Center
Georgetown University Hospital
3800 Reservoir Road
NW Washington, DC 20007
USA

2. Health professional?	3. Occupation	4. Initial reporter also sent report to FDA
☒ yes ☐ no	Physician	☐ yes ☐ no ☒ unk

3500A Facsimile

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

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Individual Safety Report
3380751-0-00-02

Continuation Sheet for FDA 3500A Form

Mfr. report # : PRIUSA1999005930

Date of this report : 10/19/99

B. Adverse event or product problem

B.5 Describe event or problem (Cont...)

and rising (laboratory value not reported). The patient was admitted to the intensive care unit where dopamine and epinephrine were required to support her blood pressure. Two days post-ingestion, the patient's mental status started to clear and she was weaned off pressor agents. However, she became edematous, febrile, and developed disseminated intravascular coagulation. Fresh frozen plasma and packed cells were administered. Antibiotics were also started for a possible aspiration pneumonitis. Three days post-ingestion, the patient went into renal and hepatic failure. Her mental status became clouded and pancuronium was administered because of agitation. Peritoneal dialysis was started. The patient then developed ARDS and despite intensive supportive care, she expired 13 days after the ingestion. Exposure to medications was acute.

C. Suspect medication (Cont...)

Seq No.
C.1 Suspect medication : 1
: TYLENOL WITH CODEINE(tablet)(ACETAMINOPHEN/CODEINE)

G. All manufacturers

8. Adverse event term(s)

6) DISSEM. INTRAVASC. COAGULATION
7) DYSPNOEA
8) PNEUMONITIS
9) AGITATION

Source of report (Literature):

Seq No. : 1
Author : Toby Litovitz
Journal title : American Journal of Emergency Medicine
Year : 88
Edition : 6
Page number : From 479 To 515
Article title : 1987 Annual Report of the American Association of Poison Control Centers National Data Collection System

OCT [illegible] 1999